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A brief intervention for addressing 'food addiction' introducing the Food Addiction Screening Tool (FAST)

Submission date
16/03/2022

Recruitment status
Suspended

Registration date
05/04/2022

Overall study status
Suspended

Last Edited
07/12/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is trying to find out if it is possible and practical to identify food addiction during a routine appointment with a dietitian.
From the research evidence, we know that some people living with obesity consider themselves to be addicted to food.
Our team would like to find out if we can ask patients about food addiction and then signpost them to a support group specifically to help with food addiction. We want to test this through a small randomised controlled trial, which will hopefully tell us if it is worth completing a bigger randomised controlled trial in the future.

Who can participate?
Anyone over 18yrs old, with a BMI >30kg/m^2; being seen by a dietitian that has enrolled in the study can participate.

What does the study involve?
The study involves at the beginning answering some questions about yourself such as your age, sex, ethnicity, and then answering 2 questionnaires and reporting your height and weight. At three and six months we will ask the same questionnaires and for your weight again.
There will be one telephone call from the researcher who will ask you how you found the study.

What are the possible benefits and risks of participating?
Possible benefits are that we are able to identify food addiction and signpost you in the right direction for support, possible risks are very low as the questions around food addiction are asked it may cause distress, however, this is very unlikely and if distress does occur the dietitians will have been trained to support.

Where is the study run from?
Coventry University (UK)

When is the study starting and how long is it expected to run for?
January 2022 to March 2024

Who is funding the study?
Coventry University (UK)

Who is the main contact?
Professor Deborah Lycett, ab5042@coventry.ac.uk

Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
304739

Study information

Scientific Title
A feasibility and acceptability study with randomised controlled trial, to explore delivery of a brief intervention – the Food Addiction Screening Tool (FAST), to address 'food addiction' in patients living with obesity (PLWO) who access dietetic services

Acronym
FAST

Study objectives
There is there a growing body of research in the domain of food addiction. Should food addiction be discussed in dietetic consultations and can food addiction screening be incorporated into dietetic consultations?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/03/2022, Coventry University Ethics Committee (Priory St, Coventry, CV1 5FB, UK; +44 24 7688 7688; ethics.hls@coventry.ac.uk), ref: P125429

Primary study design
Interventional

Study design
Feasibility randomized controlled trial

Study type(s)
Screening

Health condition(s) or problem(s) studied
Screening for food addiction in people living with obesity

Interventions

Our population group will consist of two subcategories:
1. Dietitians: Only Registered Dietitians delivering tier 3 or 4 weight management clinics or diabetes clinics in the NHS will be included
2. Service users

Participants will be randomised to the intervention or control arm.

At baseline both arms will be asked to fill in a consent form, basic demographics, Yale food addiction scale (YFAS), and a Spirituality well-being scale (SWBS). Additionally, they will be asked to self-report height and weight.

At three and six months both arms will be asked to complete the YFAS and SWBS and report weight in order to calculate BMI.

Two weeks after the intervention arm has received the FAST intervention, they will be interviewed to explore how acceptable they found receiving the FAST intervention. This topic guide will be informed by the Theoretical Framework of Acceptability.

After all, participants have received the FAST intervention, the dietitians will be invited to a brief interview where we will explore how acceptable they found giving the FAST intervention. This topic guide will be informed by the Theoretical Framework of Acceptability.

The control group will receive treatment as usual, which is an initial assessment with the dietitian regarding weight management support.

Sample size: we aim to recruit 40 people, 20 in each arm, to test this intervention's feasibility.

Randomisation will be in the form of individual randomisation, using stratified randomisation that ensures an even spread of intervention and control within different dietitian clinics. The researchers will not be involved in this procedure; this process will be under the supervision of a statistician who will provide sealed envelopes. The lead researcher will be blinded to the allocation of the patients but will be on-site to ensure the envelopes are handed out correctly.

Intervention Type

Behavioural

Primary outcome(s)

Feasibility outcome measures:
1. Recruitment rates are measured by the number of participants recruited during the recruitment period which is a six-month period
1.1 Retention rates are measured by the percentage of participants enrolled into the study that complete both post intervention (2 weeks) and follow up questionnaires (3 and 6 months)
2. Adherence will be measured through qualitative assessments of receipt and enactment which explore whether a participant has understood the content of the consultation with the dietitian and how they have responded to the advice provided (eg. whether they attended the recommended support group) this will be measured at 2-week post intervention through telephone interview
3. Time required to recruit service users measured by the number of months it will take to recruit our sample size
4. Attrition will be measured by how many participants remain in the study until the end of

follow up at 3 and 6 months
5. Fidelity of training and delivery (Dietitians): Dietitians will be audio-recorded delivering the intervention. Transcripts will be checked to see if dietitians delivered the 'food addiction' Screening Tool (FAST) interventions trained for
6. Dietitian Acceptability: After all patients have received the FAST intervention dietitians will be interviewed to explore how acceptable they found delivering the FAST intervention. Topic guide will be informed by the theoretical framework of acceptability (TFA).
7. Patient Acceptability: Two weeks after the patients receive the FAST intervention they will be interviewed to explore how acceptable they found receiving the FAST intervention. Topic guide will be informed by TFA
8. Fidelity of receipt and enactment (Patient): Two weeks after patients the FAST intervention they will also be asked questions around receipt (the extent to which participants initially engaged with and understood the intervention), and enactment (extent to which patients apply the intervention as intended in 'real life')

Key secondary outcome(s)
Measured by a self-reported questionnaire via online Qualtrics at baseline, three months, and six months after consent.
1. Addictive eating behaviour as measured by Yale Food Addiction Scale
2. Self-reported anthropometric measures weight (kg); height (cm); BMI (kg/m²)
3. Spiritual well-being is measured by the Spiritual Well-being scale

Completion date
01/03/2024

Eligibility

Key inclusion criteria
1. Attending outpatient clinic of a participating dietitian
2. ≥18 years of age
3. BMI >30kg/m²
4. Is willing and able to provide informed consent to participate and adhere to the study procedures
5. Able to read and speak English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. <18 years of age
2. BMI <30kg/m²
3. In a current episode of anorexia nervosa, e.g. self-imposed anorexia nervosa with rapid weight loss, this would require immediate referral to an ED team.
4. Likely to have bariatric surgery in the next six months or have had bariatric surgery in the last 12 months as this will skew the outcome of BMI and weight.
5. Pregnant or planning to become pregnant in the next six months as this will skew the outcome of BMI and weight.
6. Unable to consent or adhere to study procedures
7. Not able to read or speak English
8. Any situation where it is or becomes inappropriate for the RD to signpost to OA, e.g. in end stages of disease; significantly distressed by circumstances that would mean the brief intervention is unethical or insensitive at this time

Date of first enrolment
04/09/2022

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospital (coventry)
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Sponsor information

Organisation
Coventry University

ROR
https://ror.org/01tgmhj36

Funder(s)

Funder type
University/education

Funder Name
Coventry University

Alternative Name(s)
CU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date